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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,871	11/05/2003	Renfeng Guo	UM-08443	6716

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	
MAIL DATE	**DELIVERY MODE**
09/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,871	GUO ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 08/30/07 has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 08/30/07 in response to the final Office Action mailed 06/06/07.

Status of Claims

3) Claim 26 has been amended via the amendment filed 08/30/07.

Claims 26 and 27 are pending and are under examination.

The Ward Declaration

4) Acknowledgment is made of Applicants' submission of the Ward Declaration filed 08/30/07 under 37 CFR 1.132. The declaration states that none of the listed authors of the reference of Reidemann *et al. J. Clin. Invest.* 7: 110, July 2002 other than Ward, Reidemann, Guo, and Sarma were involved with the inventive process relating to the invention. The declarant states that Ward, Reidemann, Guo, Lang, and Sarma are the inventors of the subject matter embodied in the instant patent application.

Prior Citation of Title 35 Sections

5) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

6) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

7) The rejection of claims 26 and 27 made in paragraph 18 Office Action mailed 06/06/07 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the base claim.

8) The rejection of claims 26 and 27 made in paragraph 19 Office Action mailed 06/06/07 under 35 U.S.C § 102(b) as being anticipated by Morgan *et al.* (US 5,480,974 – Applicants' IDS), is withdrawn in light of Applicants' amendment to the base claim.

9) The rejection of claims 26 and 27 made in paragraph 21 Office Action mailed 06/06/07 under 35 U.S.C § 103(a) as being unpatentable over Riedemann *et al.* (*J. Clin. Invest.* 110: 101-108, July 2002 – Applicants' IDS) in view of Werfel *et al.* (*J. Immunol.* 157: 1729-1735, 1996) or Rothermel *et al.* (*Scand. J. Immunol.* 52: 401-410, 2000) and Behnke *et al.* (US 5,573,921), is withdrawn. A modified rejection is set forth below to address the claims as amended.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

10) Claim 26, and claim 27 that depends therefrom, are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 26, as amended, includes the added limitation: 'under conditions such that said subject's survival is increased'. However, there appears to be no descriptive support in the specification, as originally filed, for this added limitation. Applicants do not point to specific parts of the specification that provide descriptive support for the new limitation. The specification as filed provides descriptive support for said subject's survival being 'prolonged'. The 'conditions' under which a subject suffering from sepsis is administered with the recited monoclonal antibody that specifically binds to C5a receptor lack descriptive support. Therefore, the above-identified limitation in the claim is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitations identified above, or alternatively, remove the new matter from the claim. Applicants should specifically point out the support for any amendment made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

11) Claims 26 and 27 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention

(a) Claim 26 is vague, indefinite, and confusing in the limitation 'under conditions such that said subject's survival is increased'. What kind of conditions are encompassed in the term 'conditions' and what do Applicants mean by 'subject's survival is increased' is unclear. Does the latter mean that survival rate is increased, or subject's survival is improved or enhanced? Clarification is requested.

(b) Claim 27, which depends from claim 26, is also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 103

12) Claims 26 and 27 are rejected under 35 U.S.C § 103(a) as being unpatentable over Huber-Lang *et al.* (*The FASEB J.* express article, Published online 01/19/2001) Riedemann *et al.* (*J. Clin. Invest.* 110: 101-108, July 2002 – Applicants' IDS) in view of Werfel *et al.* (*J. Immunol.* 157: 1729-1735, 1996, already of record) or Rothermel *et al.* (*Scand. J. Immunol.* 52: 401-410, 2000, already of record) and Behnke *et al.* (US 5,573,921, already of record).

Instant claims are granted the effective filing date of the instant application, and therefore Riedemann *et al.* qualifies as prior art under subsection (b) of 35 U.S.C § 102, and accordingly is not disqualified under U.S.C 103(a).

Riedemann *et al.* taught a method of treating mice suffering from sepsis comprising administering to said mice an anti-C5aR polyclonal antibody that blocks C5aR which method resulted in a significant overall 7-day survival of 76% (i.e., increase in survival) compared to control mice that were treated with normal IgG which showed an overall survival of 0% by day 5. The anti-

C5aR antibody treatment of septic mice significantly reduced IL-6 and TNF-alpha levels and a significant reduction of aerobic bacterial counts in the lungs and kidneys when compared with control IgG-treated mice. See paragraph bridging pages 105 and 106; Figures 6 and 7; and first full paragraph in right column of page 102.

The method of Riedemann *et al.* differs from the instant invention in that the antibody administered is not a monoclonal antibody.

However, the monoclonal antibodies that bind specifically to C5a receptor (C5aR) were already known in the art at the time of the invention. For instance, Werfel *et al.* taught five anti-C5aR monoclonal antibodies (see abstract).

Similarly, Rothermel *et al.* taught the monoclonal antibody R63 that specifically binds to C5aR. See abstract; paragraph bridging the two columns on page 402 and on page 407; and paragraph bridging pages 403 and 404.

Behnke *et al.* disclosed the numerous advantages of monoclonal antibodies over polyclonal antibodies by teaching that monoclonal antibodies can be obtained in large amounts and at a high degree of purity; the mAbs are homogeneous in terms of the antigen reactivity and their properties are the same in each batch prepared; and hybridoma cell lines from which they are produced can be stored for several years without loosing their specific properties. See lines 9-17 in column 2.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace the anti-C5aR polyclonal antibody in Riedemann's method with the already art-known Werfel's or Rothermel's anti-C5aR monoclonal antibody to produce the method of the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of providing abundant amounts of anti-C5aR antibodies of high purity and homogeneous antigen reactivity as taught by Behnke *et al.* Replacement of one art-known antibody having specific binding to C5aR with another, alternative, art-known antibody having the same specificity was well within the realm of routine experimentation, would have been obvious to one of ordinary skill in the art, and would have brought about similar results or effects.

Claims 26 and 27 are *prima facie* obvious over the prior art of record.

Remarks

13) Claims 26 and 27 stand rejected.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives facsimile transmissions 24 hours a day and 7 days a week.

15) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

16) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

S. DEVI, PH.D.
PRIMARY EXAMINER

September, 2007